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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 626,935	09 07 2000	Jan Krzysztof Blusztajn	GI 5372A	2376

7590 07 09 2002

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EXAMINER

BAKER, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 07 09 2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/656,935

Applicant(s)

BLUSZTAJN ET AL.

Examiner

Anne-Marie Baker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

The preliminary amendment filed March 18, 2002 (Paper No. 6) has been entered.

Claims 1-16 are pending in the instant application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, drawn to a pharmaceutical composition comprising BMP-9, classified in class 530, subclass 350.
- II. Claims 15 and 16, drawn to a pharmaceutical composition comprising BMP-2, classified in class 530, subclass 350.
- III. Claims 15 and 16, drawn to a pharmaceutical composition comprising BMP-4, classified in class 530, subclass 350.
- IV. Claims 15 and 16, drawn to a pharmaceutical composition comprising BMP-6, classified in class 530, subclass 350.
- V. Claims 15 and 16, drawn to a pharmaceutical composition comprising BMP-7, classified in class 530, subclass 350.
- VI. Claims 15 and 16, drawn to a pharmaceutical composition comprising BMP-12, classified in class 530, subclass 350.
- VII. Claims 7, 9, 11, 12, and 14, drawn to a method for *in vivo* differentiation or *in vivo* upregulation of particular genes, classified in class 514, subclass 2.
- VIII. Claims 8, 10, and 13, drawn to a method of cell therapy, classified in class 424, subclass 93.1 and class 424, subclass 93.21.

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Claims 15 and 16 embrace the inventions of Groups II-VI. Should any one of Groups II-VI be elected, Claims 15 and 16 will be examined only to the extent that they encompass the elected subject matter.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI are patentably distinct, one from the other, because the inventions are drawn to distinct compositions that are not obvious variants. The compositions of the inventions of Groups I-VI comprise structurally different polypeptides. The polypeptides are structurally, chemically, biologically and functionally distinct, one from the other. The polypeptides are not obvious one over the other. Thus, the compositions of the inventions of Groups I-VI are patentably distinct, each from the other.

Inventions I-VI and inventions VII-VIII are patentably distinct, one from the other, because the inventions are drawn to distinct compositions and materially different methods. The compositions of the inventions of Groups II-VI are not required for and cannot be used for the methods of the inventions of Groups VII and VIII. Although the composition of the invention of Group I can be used in the method of Group VII, its use is not limited to *in vivo* administration to a patient, as the composition can also be used to differentiate cells *in vitro* prior to cellular transplantation, as in the method of the invention of Group VIII. Thus, the compositions of the inventions of Groups I-VI are patentably distinct from the methods of the inventions of Groups VII-VIII.

Inventions VII and VIII are patentably distinct, each from the other, because the inventions are drawn to materially different methods that require different starting materials, different modes of operation, and produce different effects. The method of the invention of Group VII requires as starting materials a BMP-9-containing composition and a patient in need of cholinergic neurons, whereas the method of the invention of Group VIII requires as starting materials a BMP-9-containing composition, embryonic basal forebrain cells, and a patient having Alzheimer's disease or malfunctioning cholinergic

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neurons. Methods of cell transplantation therapy have a substantially different and distinct mode of operation from methods of protein therapy and produce different effects at the cellular/biochemical level and typically at the level of clinical symptoms as well. Furthermore, methods of cell transplantation requires consideration of issues not relevant to and not required for methods of protein therapy. Thus, the method of the invention of Group VII is patentably distinct from the method of the invention of Group VIII, and vice versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Baker whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Anne-Marie Baker, Ph.D.

Anne-Marie Baker
ANNE-MARIE BAKER
PATENT EXAMINER